PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference PH-2429-PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/005803	29.03.2005	31.03.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant
TORAY INDUSTRIES, INC.

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP Facsimile No.	Authorized officer Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/005803

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/005803

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-8, 13, 14, 16	YES
	Claims	1-3, 9-12, 15, 17, 18	NO
Inventive step (IS)	Claims		YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP 2003-501631 A (Zeptosens AG), 14 January 2003
Document 2: JP 2001-316298 A (Japan Science & Technology Corp.), 13 November 2001 & EP 1262555 A & US 2003/0092069 A

Claims 1-3, 9-12, 15, 17, 18

Document 1 describes a regaent comprising a vesicle, a polymer molecule and a recognizing element, along with a detection method using this reagent. It describes that the recognizing element binds to the polymer molecule (Claim 3, etc.), and that the polymer molecule binds to the vesicle by means of a membrane protein or other anchor molecule (paragraph 0056), and gives antibodies, antibody fragments, enzymes and membrane receptors as examples of recognizing elements (Claim 2, etc.). It also describes joining an additional label selected from luminescence labels, fluorescent labels and the like to the vesicle (Claim 10, etc.). Moreover, it describes using a waveguide as a sensor platform (Claim 18, etc.).

Since the polymer molecule described in document 1 has the effect of reinforcing the vesicle, it is also capable of forming a vesicle (particle). Consequently, the inventions of Claims 1, 3, 9-12, 15, 17 and 18 are not novel because they are equivalent to the reagents and detection methods described in document 1.

Claims 4-8

Document 2 describes forming a hollow nanoparticle by using a yeast or the like to express a protein having particle formability, such as a hepatitis B surface antigen.

Since documents 1 and 2 both relate to vesicle-forming technology, adopting those described in document 2 for the polymer molecule and lipid membrane in document 1 would be an obvious matter to a person skilled in the art.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/005803

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V

Claims 13, 14, 16

Conventionally, various locations have been used for introducing labelling particles when labelling vesicles (see conventional examples in document 1). When introducing the additional label into the vesicle in document 1, binding it to the substance recognizing molecule or polymer or enclosing it inside the vesicle would be an obvious matter to a person skilled in the art.